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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/781,046	02/08/2001	Kangsheng Wang	258/193	9275

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EXAMINER

TON, THAIAN N

ART UNIT PAPER NUMBER

1632

DATE MAILED: 11/30/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/781,046

Applicant(s)

WANG, KANGSHENG

Examiner

Thaian N. Ton

Art Unit

1632

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
 - If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
 - If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
 - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 15 September 2004.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-26 is/are pending in the application.
- 4a) Of the above claim(s) 1-21 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 22-26 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

DETAILED ACTION

Applicants' Response, filed 9/15/04, has been entered. Claim 22 has been amended. Claims 1-26 are pending. Claims 1-21 are withdrawn without traverse in Paper No. 6. Claims 22-26 are under current examination.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

The prior rejection of claims 22-26 under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement is maintained for reasons of record. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

Applicants argue that, with regard to the prior Office action, the Wang declaration makes it clear that each sub-supernatant was derived from a different hybridoma, that it is immaterial whether the antibodies disclosed in the Declaration recognize the same or different epitopes, and that it is well-established that two different monoclonal antibodies with very different amino acid sequences may be capable of binding the same epitope. However, Applicants state that to advance prosecution, they provide written assurance that an acceptable deposit will

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be perfected on or before the date of payment of the issue fee. See p. 6, last ¶ of the Response.

The rejection of the claims is maintained because the deposit has not been perfected, and outstanding rejections under 112, 1st paragraph, for enablement, remain. The Examiner notes that, for the record, an acceptable deposit is considered the deposit of monoclonal antibody C (mAbC) as stated in the prior rejections, wherein the deposit will be perfected on or before the date of payment of the issue fee.

Once the deposit has been perfected, the claims will be limited the antibody, mAbC, which is characterized by having binding affinity to sperm cells from a plurality of species of animals, wherein a sperm cell bound with the antibody mAbC retains the ability to fertilize an oocyte.

The prior rejection of the claims, with regard to the enabled scope is maintained because the claims, as amended recite, "the antibody comprises monoclonal antibody mAbC." Thus, this language is considered open language, MPEP § 2111.03 states, "[C]omprising' leaves the claim open for the inclusion of unspecified ingredients even in major amounts". Thus, this claim language encompasses antibodies other than mAbC, which is not found to be the enabled scope of the invention. This is further exemplified in the dependent claims, for example, the antibody is further characterized to have certain properties, such as

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the ability to bind to sperm cells from a plurality of species of animal. It is maintained that the state of the art of antibodies is such that one of skill in the art would expect such antibodies to inhibit fertilization for reasons of record advanced in prior Office actions. The state of the art at the time the claimed invention was replete with art showing that antibodies directed to sperm was such that one would expect the inhibition of fertilization. [See Yan, Nakamura, Naz and Kim, all cited in prior Office actions]. As such, when taken with the state of the art and lack of teaching in the specification for the generation of sperm-specific antibodies which, when bound to a sperm, would allow a sperm to retain the ability to fertilize an oocyte, other than the exemplified mAbC, it is maintained that the claimed invention is enabled only for the antibody mAbC.

Accordingly, when taken with state of the art of sperm-specific antibodies, with particular regard to the inhibition of fertilization, and the quantity of experimentation necessary for the production and use of the antibody characterized by having binding affinity to a sperm cell, wherein the sperm cell bound with the antibody retains the ability to fertilize an oocyte, would have required undue experimentation for one skilled in the art to make and/or use the claimed invention.

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Conclusion

No claim is allowed.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Thaian N. Ton whose telephone number is (571) 272-0736. The Examiner can normally be reached on Monday through Friday from 8:00 to 5:00 (Eastern Standard Time), with alternating Fridays off. Should the Examiner be unavailable, inquiries should be directed to Amy Nelson, Acting SPE of Art Unit 1632, at (571) 272-0804. Papers related to this application may be submitted to Group 1600 by facsimile transmission. Papers should be faxed to Group 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). The CM1 Fax Center number is (703) 872-9306.

twt

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